

FOOD SAFETY AND SECURITY

Operational Risk Management

**DHHS,
US Food and Drug Administration,
Center for Food Safety and
Nutrition**

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FOOD SAFETY AND SECURITY

**Vision: Public Health Protection through
Safe Food and water sources**

**Strategy: Stop attacks and also reduce
vulnerability to them before they
occur**

- **We will accomplish this through:**
 - **Identifying our food assets**
 - **Identify potential threats**
 - **Use ORM for food safety and security**
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FOOD SAFETY AND SECURITY

National Food and Agriculture Assets

- ✓ U.S. agriculture has a \$1 trillion value and provides 22 percent of all jobs. Production exceeds \$200 billion with over \$55 billion in exports.
 - ✓ Production: Over 500,000 farms
 - ✓ Processing: 57,000 food; 6,000 meat, poultry, egg
 - ✓ Distribution
 - ✓ Transportation
 - ✓ Retail: Over 1.2 million
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Identify Potential Threats

- ✓ **The DOD January 2001 Proliferation: Threat and Response report for the first time identified that attacks against the U.S. food supply could affect the economic stability of the country and erode military readiness.**
 - ✓ **FBI and law enforcement gathers information for composite picture of threat conditions**
 - ✓ **Examples of analysis: Existence, Capability, Intention, Demonstrated terrorist activity over time, Security environment, Targeting**
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Identify Potential Threats

- ✓ **Aggressor: Criminals, terrorists, protesters, subversive, disgruntled insider**
 - ✓ **Tactics: Exterior attacks, Forced entry, covert entry, insider compromise**
 - ✓ **Type of agents: Chemical, Biological, Radiological and Physical**
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ORM FOR FOOD SAFETY AND SECURITY

What is ORM? It is a 6-step sequence to increase operational effectiveness by anticipating hazards and reducing the potential for loss.

Purpose of ORM The purpose of ORM is to minimize risks to acceptable levels, proportional to mission accomplishment

Benefits of ORM Provides more effective use of resources reduce mishaps and can be used to improve food safety and security.

Origin of ORM The concept grew out of idea developed to improve safety and reduced losses in aircraft, space vehicles and nuclear power.

FOOD SAFETY AND SECURITY RISK COMPARISON

TRADITIONAL	ORM
Random, individual Dependent	Systematic
Common Sense	Methodical
Uninformed Decision	Decision based on risk vs. benefit
Compliance Based	Involvement & Empowerment
Reactive	Proactive

FOOD SAFETY AND SECURITY ORM



FOOD SAFETY AND SECURITY ORM PROCESS DEFINITIONS

- 1. *Flow Diagram:*** List of food production events in sequence
 - 2. *Hazards:*** Conditions with the potential to cause illness, injury or death, property damage or mission degradation
 - 3. *Risk:*** An expression of possible loss in terms of severity and probability that may result from hazards
 - 4. *Risk assessment:*** Identifying hazards and determining impact on mission (high risk, low risk)
 - 5. *Risk management:*** Analyze and implement risk control decisions
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FOOD SAFETY AND SECURITY ORM Rules

- 1. Accept no unnecessary risk**
 - 2. Make risk Decisions at the Appropriate Level**
 - 3. Accept risk when benefits outweigh the costs**
 - 4. Integrate ORM into policies and planning at all levels**
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Understand Unnecessary risk

- 1. Some degree of risk is a fundamental reality**
 - 2. Risk management is a process of tradeoffs, keep problems in perspective**
 - 3. Weigh risks and make judgments based on knowledge, experience, and requirements**
 - 4. There is no best solution. Use good judgment**
 - 5. Complete safety is a condition that seldom can be achieved in a practical manner**
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Step 1. Identify where Hazards can be introduced.

Purpose: To get a hazard survey of all phases of an operation

Method: Conduct on site review of each activity or event in food production process.

✓ **Use the “What If” Tool to capture input of operating personnel**

✓ **Assess hazards at each step or activity (detect root systemic cause factors)**

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Step 1. Identify where Hazards can be introduced.

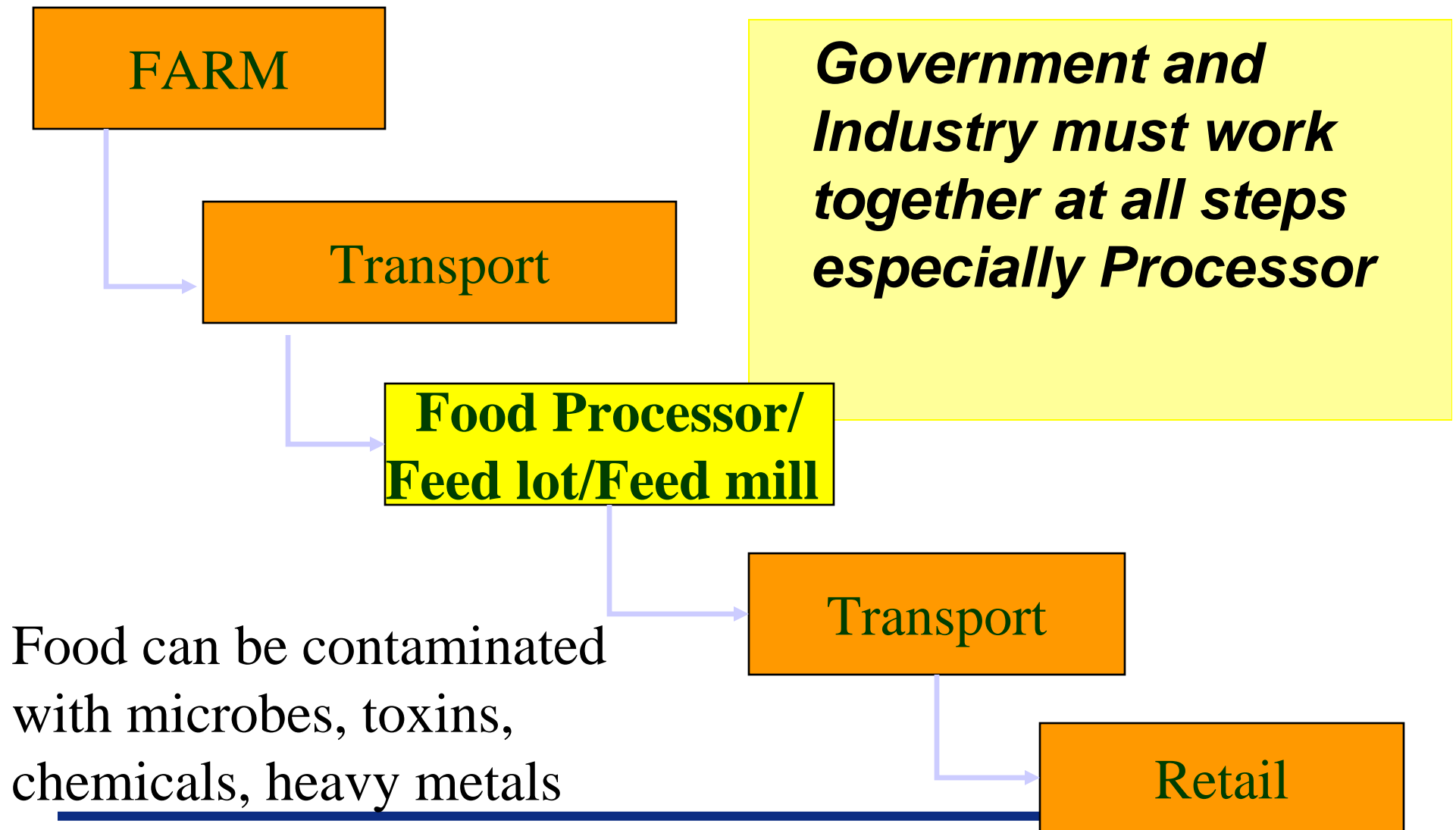
Mission: The desired outcome (food safety and security)

Management: Directs the operation by defining standards, procedures and controls. Management process cited in 80 percent of reported mishaps other root (systemic) cause factors for mishaps:

- ✓ **People:** Most common root cause, doesn't know (training)
Doesn't care (motivation) can't do (selection)
 - ✓ **Machines:** Poor design, poor performance, repairs not made, not used as intended, no upkeep or replacement
 - ✓ **Environmental forces:** Weak facility design, lighting, noise, Temperature, ventilation, contamination,
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FOOD PRODUCTION FLOW DIAGRAM



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Step 1. IDENTIFY THE HAZARD

Activity/Event	Hazard
Fresh vegetables grown on farm	Many employees with multiple tasks and no ID badges (1)
Transported in refrigerated truck	Trucks are not secure; no security in hiring drivers (2)
Food Processor/transport	Water used to clean product is not potable (3)
Stored in restaurant	No locks, exterior door unsecured 4
Food preparation	New employees no background check, on midnight shift, given locker required to have own lock 5

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ASSESS THE HAZARDS SEVERITY

- ***CATASTROPHIC***—Complete business failure, death.
 - ***CRITICAL***—Major business degradation, severe injury and illness.
 - ***MODERATE***—Minor business degradation, minor injury or illness.
 - ***NEGLIGIBLE***—Less than minor business degradation, less than minor injury or illness
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ASSESS THE HAZARDS PROBABILITY

- ***Frequent***-Occurs often in career to individual and population is continuously exposed
 - ***Likely***-Occurs several times in a career and population are exposed regularly
 - ***Occasional***-Will occur in a career and occurs sporadically in a population
 - ***Seldom***-May occur in a career and occurs seldom in a population
 - ***Unlikely***- So unlikely you can assume it will not occur in a career and occurs very rarely in a population
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Operational Risk Assessment Matrix

STEP 2: ASSESS THE RISK

			PROBABILITY				
			Frequent	Likely	Occasional	Seldom	Unlikely
			A	B	C	D	E
SEVERITY	Catastrophic	I	Extremely High		High		Medium
	Critical	II	Extremely High	High		Medium	Low
	Moderate	III	High	Medium		Low	
	Negligible	IV	Medium				
			Risk Levels				

Operational Risk Assessment Matrix

STEP 2: ASSESS THE RISK

			PROBABILITY				
			Frequent	Likely	Occasional	Seldom	Unlikely
			A	B	C	D	E
SEVERITY	Catastrophic	I	1	2	6	8	12
	Critical	II	3	4	7	11	15
	Moderate	III	5	9	10	14	16
	Negligible	IV	13	17	18	19	20
			Risk Levels				

Step 2. Assess the Risk

Hazard Identified	Assess the Risk	Risk Level
Trucks are not secure; no security in hiring drivers	New employees hired Could be aggressors. Could contaminate product harm people, machines, facility	
New employees no background check, on midnight shift, given locker required to have own lock	New employees hired Could be aggressors. Could contaminate Product, harm people, Machines, facility	

Step 2. Assess the Risk

Hazard Identified	Assess the Risk	Risk Level
Trucks are not secure; no security in hiring drivers 2	New employees hired Could be aggressors. Could contaminate product harm people, machines, facility	Critical seldom Medium 11
New employees no background check, on midnight shift, given locker required to have own lock 5	New employees hired Could be aggressors. Could contaminate Product, harm people, Machines, facility	Critical seldom Medium 11

Step 2. Assess the Risk

Hazard Identified	Assess the Risk	Risk Level
Water used to clean product is not potable 3	Could result in Contaminated product	
No locks, exterior door from kitchen is unsecured (4)	Aggressors could enter from exterior door contaminate product, harm people, Machines, facility	

Step 2. Assess the Risk

Hazard Identified	Assess the Risk	Risk Level
Water used to clean product is not potable	Could result in Contaminated product	Critical Likely High 4
No locks, exterior door from kitchen is unsecured	Aggressors could enter from exterior door contaminate product, harm people, Machines, facility	Critical Likely High 4

Step 3. Analyze Risk Control Measures

- ✓ **Reject: Refuse the risk**
 - ✓ **Avoid: Cancel job**
 - ✓ **Delay: delay a risk**
 - ✓ **Transfer: spread loss to another**
 - ✓ **Spread: increase exposure time**
 - ✓ **Compensate: redundant capabilities**
 - ✓ **Reduce: Plan systems without hazards**
 - ✓ **Incorporate safety devices**
 - ✓ **Provide warning devices**
 - ✓ **Develop procedures and training**
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Step 3. Analyze Risk Control Measures

Hazard	Risk Control	Rank
Aggressors could enter from exterior door contaminate product, harm people, Machines, facility	-Post the door with signs that identify not an exit	2
	-Put up security cameras	3
	-Put guard on door	4
	-provide warning device and Install a panic bar	1
New employees hired Could be aggressors. Could contaminate Product, harm people, Machines, facility	Reject the risk. -Put new hires on day shift for first 90 days Do periodic background checks and provide locks	1

Step 4. Make Risk Control Decisions

Hazard	Risk Control	Rank
Aggressors could enter from exterior door contaminate product, harm people, Machines, facility	-provide warning device and Install a panic bar	1
	-Post the door with signs that identify not an exit	2
	-Put up security cameras	3
	-Put guard on door	4
New employees hired Could be aggressors. Could contaminate Product, harm people, Machines, facility	Reject the risk. -Put new hires on day shift for first 90 days Do periodic background checks and provide locks	1

Step 5. And 6.

Step 5. Implement Risk Control Decision

- **Make assets available to implement specific controls**
- **Inform personnel in the system**
- **Provide management support**
Award programs etc

Step 6. Supervise and Review

- **Monitor effectiveness of control actions**
 - **Provide feedback system (audits etc)**
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Food Safety and Security: Threats and Opportunities

Questions?
